

## Response to Criticism of the Amendment

The examiner argues that the amendments to the claims filed with the 03/30/2004 preliminary amendment were not in the proper order as now required by 37 CFR 1.121(c). The applicant now provides the required separate sheet with the claims properly listed and identified.

### Rejection of Claims Under 35 USC 112(2d)

The examiner claims not to be clear whether the device or the tissues are to be coated in claim 45. Claim 45 is now amended to make this clear.

### Rejection of Claims Under 35 USC 102(b)

The examiner rejects claim 45 as anticipated by Shikani et al 1998. This reference is said to disclose a transplantable medical device coated with an anti-inflammatory composition. The examiner is reminded that the inflammatory composition is accompanied by an anti-infection composition, and that both are embedded in a polymer for coating purposes, factors of distinction compared to the present claims.

Present claim 45 has a different set of claim elements than in the Shikani system. Present claim 45 does not claim an anti-infective agent as part of the coating, and critically, claim 45 coating composition includes a flavonoid compound, not mentioned in Shikani.

The examiner is reminded that, under well-settled law, for a reference to be valid 102(b) prior art, it must contain all of the elements of the claim under consideration. [A prior art reference under 35 U.S.C. § 102 is said to "anticipate" a claimed invention if each and every element of the claimed invention is disclosed, y, in the prior art reference. *In re Spada*, 911 F.2d 705, 708, 15 USPQ2d 1655, 1657 (Fed. Cir. 1990); *Constant v. Advanced Micro-Devices, Inc.*, 848 F.2d 1560, 1570, 7 USPQ2d 1057, 1064 (Fed. Cir.), cert. denied, 488 U.S. 892 (1988); *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989), cert. denied, 493 U.S. 853 (1989). In deciding the issue of anticipation, the trier of fact must identify the elements of the claims, determine their meaning in light of the specification and prosecution history, and identify corresponding elements disclosed in the allegedly anticipating reference. *Lindemann Maschinenfabrik v. American Hoist and Dairy Co.*, 730 F.2d 1452, 1458-59, 221 USPQ 481, 485-86 (Fed. Cir. 1984).]

It is clear that, under the law, Shikani is not an anticipatory reference.

### Rejection of Claims Under 35 USC 103a).

The examiner rejects all claims on an assertion that they are obvious over Morrison *et al* and Hwang *et al* in view of Theoharides,

Morrison discloses medical devices coated with an active condroitin sulfate A and/or C. This reference does not disclose the flavonoids in the coated devices, which is a critical element of applicant's claim 45. The examiner attempts to cure this deficiency of Morrison by citing Hwang *et al.* which uses flavonoids to treat cystic fibrosis.

In combining references to make out a *prima facie* case of obviousness, the examiner is obliged to show by reference to specific evidence in the cited references that there was (i) a suggestion to make the combination and (ii) a reasonable expectation that the combination would succeed. Both the suggestion and reasonable expectation must be found within the prior art, and not be gleaned from applicants' disclosure. In re Vaeck, 20 USPQ2d 1438, 1442 (Fed. Cir. 1991); In re Dow Chemical Co., 5 USPQ2d 1529, 1531 (Fed. Cir. 1988).

Hwang is a clinical disclosure concerned with the use of flavonoids to treat cystic fibrosis in humans. The examiner is incorrect in asserting that Hwang discloses coated devices. The clinical use of flavonoids to treat cystic fibrosis is totally non-analogous to the use of the drug to coat medical devices. As stated by In re Deminski.796 F.2d436,230 USPQ 313 (Fed. Cir. 1895), there is a two-step test for whether a reference is analogous or non-analogous art: (1) is the reference within the same or a different field? and, (2) if not, whether the reference is reasonably pertinent to the particular problem with which the inventor was involved. The two different uses would be in totally different search classes, and an inventor working with coating implantable medical devices would be unlikely to consider a reference concerned with the clinical *in vivo* use of a composition to treat a human disease.. Hence, the Hwang reference cannot be used in conjunction with the Morrison reference to support a 103 rejection of applicant's claims.

Having failed to combine Hwang with Morrison, the examiner then turns to applicant's published patent application 20020176902 (filed 1/30/2001) for "in view of" obviousness support.

This Theoharides reference discloses a *dietary composition* containing a proteoglycan sulfate plus, optionally, one or more of a group of compounds consisting of hexosamine sulfate, flavone, olive kernel extract, S-AM and diphenylhydramine.

This reference, like Hwang et al., is non-analogous art and therefore cannot support the examiner's 103 rejection. This reference teaches only a dietary composition, which is in an entirely different search class than implantable medical devices. This reference provides no motivation other than the inhibition of the secretion of inflammatory biomolecules from mast cells (see claim 1). There is no motivation within this reference towards implantable medical devices.

**Secondary considerations:**

Under *Graham*, objective evidence of nonobviousness includes commercial success. *Custom Accessories, Inc. v. Jeffrey-Allan Industries, Inc.*, 807 F.2d 955, 1 USPQ2d 1196 (Fed. Cir. 1986). This patent application, among many other of applicant's applications and issued patents, plus corresponding trademarks have been licensed by Algonot, Inc., 5111 Ocean Blvd., Ste. C, Sarasota, FL34242, and sales of the products are net over \$10M. An accompanying Declaration from Algonot demonstrates that this company has licensed the present technology, and will go forward with it when this patent is granted. Clearly, this is commercial success.

Thus, contrary to the examiner's assertion, it was not *prima facie* obvious to combine these three references to reach applicant's invention. It is respectfully requested that the rejections be withdrawn.

Respectfully submitted,

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